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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,817	05/13/2002	Jacques Edouard Germond	112843-039	9937
29174	7590	09/16/2004	EXAMINER	
BELL, BOYD & LLOYD, LLC			KERR, KATHLEEN M	
P. O. BOX 1135			ART UNIT	PAPER NUMBER
CHICAGO, IL 60690-1165			1652	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/019,817

### Applicant(s)

GERMOND ET AL.

### Examiner

Kathleen M Kerr

### Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-24,26-36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-24,26-36 and 38 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/20/01 (originally) is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/21/03, 8/18/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: copies of seq listings.

## **DETAILED ACTION**

### ***Application Status***

1. A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on March 15, 2004 has been entered.

2. In response to the previous Office action on the merits, an Advisory action (January 14, 2004), Applicant filed a request for continued examination (RCE) and an amendment received on March 15, 2004. Applicant also submitted a sequence listing with a subsequent filing on July 1, 2004. Said amendment amended the specification and cancelled Claim 25. Thus, Claims 20-24, 26-36 and 38 are pending in the instant Office action and will be examined herein.

### ***Priority***

3. As previously noted, the instant application is granted the benefit of priority for the European application 99112471 filed on June 30, 1999 and International Application No. PCT/EP00/05834 filed on June 23, 2000.

### ***Information Disclosure Statement***

4. The information disclosure statements filed on July 21, 2003 and August 18, 2003 have been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copies.

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***Compliance with the Sequence Rules***

5. By virtue of Applicant's amendment to the specification identifying sequences in the figures, the application now fully complies with the sequence rules. **See "Allowance" below concerning the need to submit a corrected sequence listing.**

***Drawings***

6. The drawings are considered **informal** for the reasons detailed in the attached copy of PTO Form 948. **Appropriate correction is required in response** to the instant Office action and may not be held in abeyance (see 37 C.F.R. § 1.85(a)).

***Withdrawn - Objections to the Specification***

7. Previous objection to the specification for being confusing with respect to the sequence listing is withdrawn by virtue of Applicant's amendment to the specification defining each and every SEQ ID NO listed in the sequence listing.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

8. Previous rejection of Claim 25 under 35 U.S.C. § 112, second paragraph, as being indefinite for the "term "catabolite responsive elements" is withdrawn by virtue of Applicant's cancellation of said claim.

9. Previous rejection of Claim 25 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's cancellation of said claim.

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*Allowance*

10. This application is in condition for allowance except for the following formal matters:

The pending sequence listing contains a typographical error in the amino acid sequence SEQ ID NO:2 that must be corrected to reflect the originally filed sequence listing.

- a) In SEQ ID NO:2, position 126 was originally filed as an arginine (“R” or “Arg”) in both the paper copy and the computer readable form (CRF). See Figure 4, original paper copy of the sequence listing filed by Applicant, and original CRF copy (USPTO print-out attached) filed by Applicant.
- b) In the sequence listing filed on December 15, 2003 in CRF and paper, the “Arg” is changed to an “Asp” for aspartate or “D”. It is noted that the encoding DNA sequence (SEQ ID NO:1) has not been changed. See paper copy and CRF copy (USPTO print-out attached) filed by Applicant on December 15, 2003.
- c) In the sequence listing filed on March 15, 2004, the CRF was defective, but the paper copy perpetuated the error in SEQ ID NO:2 as noted above. See paper copy filed by Applicant on March 15, 2004.
- d) In the sequence listing filed on July 1, 2004 in CRF and paper, the error is again perpetuated. See paper copy and CRF copy (USPTO print-out attached) filed by Applicant on July 1, 2004.

Therefore, Applicant must file a corrected copy of the sequence listing containing 33 SEQ ID NOs, in computer readable form and paper copy, wherein SEQ ID NO:2 is as originally filed (with an Arg at position 126). A statement of sameness and no new matter must accompany the sequence listing.

11. **Prosecution on the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 C.F.R. § 1.111(b) and M.P.E.P. § 707.07(a).

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A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

***Conclusion***

12. Claims 20-24, 26-36 and 38 are allowed. A corrected sequence listing and formal drawings are required in response to the instant Office action so that the application may be allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

September 13, 2004

```

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   RBS
121  ATGGCAACGATCAGAGAAGTGGCCAAGGCAGCCGGCGTGTGCGCCAGCGACGGTTTCCCGG
1  M A T I R E V A K A A G V S P A T V S R
   helix          turn          helix
181  GTCTTGAACATGACCAGACCCTGTCTGGTCAATGAGGCAACGCCGCGCAGAAGATATTCAAA
21  V L N Y D Q T L S V N E A T R Q K I F K
241  ACTGCTGAAGCCATGCACTACCATAAGAGCCGGAAGACCAGAAAGAGCAAGCAAAAGCGC
41  T A E A M H Y H K S R K T R K S K Q K R
301  CTGGCGATCTGCTGTGGTGTGACCAAGACCAGGAGATCAAGGACCTCTATTACTATTCA
61  L A I C L W C D Q D Q E I K D L Y Y Y S
361  ATCAGAACCAGCGCGCAAGCAGAGGCCAAGAAGCAGGGACTTGAAAGCCAGGTCATTAT
81  I R T S A Q A E A K K Q G L E S Q V I Y
421  CCGGCTGATCCTTTGCCGATCCAGCTGCTTAAAGCGGGATTATCATGATTGGCTACCAG
101  P A D P L P D P A A L S G I I M I G Y Q
481  CAGTATTCGCCAGACCGTTGAATGAAGTCAAAAAGTCTGGCCTGCCCTGGTCTTTGTC
121  Q Y S P D R L N E V K K S G L P L V F V
541  GATACTGACACCTTAAATTTGGGTTACTGCTCAGTTGTGGCTGACTTTGGCCAGGCCATG
141  D T D T L K L G Y C S V V A D F G Q A M
601  CAGGAGCGCTAGAGGTCTTCTGGGGGCAGGCAGGGAGCGGATCGCCCTTTTGGATGGT
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661  GATTTGACAGTAAATTTTGATAAAAACAACCTGGTTCGACTTCCGCTTCCGCGATTATAAG
181  D L D S N F D K N N L V D F R F R D Y K
721  AAGAGCCTCGCGGCCCGCGGCCAGTACGACCCGACTTAGTCTATGTTGAAACTTCACT
201  K S L A A R G Q Y D P D L V Y V G N F T
781  CCGCAATCTGGCTATGAAGCCATTAAAGAAGCTCTTAAGTCCGGCTCCTTCCCGAAAGCC
221  P Q S G Y E A I K E A L K S G S F P K A
841  TTGATTGCGGCTAATGACGCCATGGCTATTGGAGCATTGAAGGCCTTTAAAGAAGCTGGA
241  L I A A N D A M A I G A L K A F K E A G
901  ATTAAAGTCCAGAGGACGTCAGTCTGATTTCTTTAATGACACAACGGCAGCAGAATTT
261  I K V P E D V S L I S F N D T T A A E F
961  GCCAACCAGCCTTGACTAGCGTACATGTAGAGACCCAGCAGATGGGCGGAGCCAGCGTC
281  A N P A L T S V H V E T Q Q M G R A S V
1021  AAGGTCATGAAAGACCTGCTGGATGATGATGAAGCCGGCACTTACAAGGTCACCTTCCCA
301  K V M K D L L D D D E A G T Y K V T F P
1081  ACAAACTCGTTTACCGGAATCTTGCCCAAAAGCATAAGGGCATAGAGCATAATAACAG
321  T K L V Y R E S C P K A *
1141  CAAAGAAATAGCTTGGAGATTGATTTTCTCCAAGCTATTTTTCGTATATATTATGGCTGC
   stop asnA
1201  ATTCTGTTGATCATTCTTGGGAATGGGACAGCTTCACGAACGTGGTCCAGCTTGAGATC
1261  CAGGCAATGACCCGTTCAAAG

```

Figure 4:

Nucleotide and amino acid sequences of the *L. delbrueckii* subsp. *lactis* LL44 *lacR* gene. Start (121) and stop (1119) codons are boxed. Putative *lacR* RBS is underlined. The putative rho-independent terminator is underlined by convergent arrows. Stop codons of the beta-galactosidase (*lacZ*) and Asn t-RNA synthetase (*asnA*) genes are boxed. Insertion sequence of ISL3 is represented by a large open arrow. Single base pair deletion (722) in the mutant LZL102 is shown by an arrow head, leading to a premature stop codon (758) underlined.

ORIGINAL



PCT10

## RAW SEQUENCE LISTING

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PATENT APPLICATION: US/10/019,817

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 7 expression in bacterial cells  
 9 <130> FILE REFERENCE: 112843-039  
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 C--> 12 <141> CURRENT FILING DATE: 2002-05-13  
 14 <150> PRIOR APPLICATION NUMBER: 99112471.0  
 15 <151> PRIOR FILING DATE: 1999-06-30  
 17 <160> NUMBER OF SEQ ID NOS: 22  
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 29 atggcaacga tcagagaagt ggccaaggca gccggcggtg gccagcgac ggtttcccg 180  
 30 gtcttgaact atgaccagac cctgtcggtc aatgaggcaa cgcggcagaa gatattcaaa 240  
 31 actgctgaag ccatgcacta ccataagagc cggaagacca gaaagagcaa gcaaaagcgc 300  
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 35 cagtattcgc cagacggctt gaatgaagtc aaaaagctct gcctgcccct ggtctttgtc 540  
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 37 caggaggcgc tagagggtct ctgggggcag ggcagggagc ggatcgccct tttggatggt 660  
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 PATENT APPLICATION: US/10/019,817

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65 Ala Thr Arg Gln Lys Ile Phe Lys Thr Ala Glu Ala Met His Tyr His
66           35           40           45
68 Lys Ser Arg Lys Thr Arg Lys Ser Lys Gln Lys Arg Leu Ala Ile Cys
69           50           55           60
71 Leu Trp Cys Asp Gln Asp Gln Glu Ile Lys Asp Leu Tyr Tyr Tyr Ser
72  65           70           75           80
74 Ile Arg Thr Ser Ala Gln Ala Glu Ala Lys Lys Gln Gly Leu Glu Ser
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77 Gln Val Ile Tyr Pro Ala Asp Pro Leu Pro Asp Pro Ala Ala Leu Ser
78           100          105          110
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86 Leu Lys Leu Gly Tyr Cys Ser Val Val Ala Asp Phe Gly Gln Ala Met
87 145          150          155          160
89 Gln Glu Ala Leu Glu Val Phe Trp Gly Gln Gly Arg Glu Arg Ile Ala
90           165          170          175
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93           180          185          190
95 Asp Phe Arg Phe Arg Asp Tyr Lys Lys Ser Leu Ala Ala Arg Gly Gln
96           195          200          205
98 Tyr Asp Pro Asp Leu Val Tyr Val Gly Asn Phe Thr Pro Gln Ser Gly
99           210          215          220
101 Tyr Glu Ala Ile Lys Glu Ala Leu Lys Ser Gly Ser Phe Pro Lys Ala
102 225          230          235          240
104 Leu Ile Ala Ala Asn Asp Ala Met Ala Ile Gly Ala Leu Lys Ala Phe
105           245          250          255
107 Lys Glu Ala Gly Ile Lys Val Pro Glu Asp Val Ser Leu Ile Ser Phe
108           260          265          270
110 Asn Asp Thr Thr Ala Ala Glu Phe Ala Asn Pro Ala Leu Thr Ser Val
111           275          280          285
113 His Val Glu Thr Gln Gln Met Gly Arg Ala Ser Val Lys Val Met Lys
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10/01 9817

ORIGINAL

## SEQUENCE LISTING

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<120> The Lactose operon of Lactobacillus delbrueckii and its  
use for controlling gene transcription and/or  
expression in bacterial cells

&lt;130&gt; 112843-039

&lt;140&gt; PCT/EP00/05834

&lt;141&gt; 2000-06-23

&lt;150&gt; 99112471.0

&lt;151&gt; 1999-06-30

&lt;160&gt; 22

&lt;170&gt; PatentIn Ver. 2.1

&lt;210&gt; 1

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&lt;212&gt; DNA

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&lt;210&gt; 2

&lt;211&gt; 332

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&lt;213&gt; Lactobacillus delbrueckii

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Thr Val Ser Arg Val Leu Asn Tyr Asp Gln Thr Leu Ser Val Asn Glu  
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 35 40 45

Lys Ser Arg Lys Thr Arg Lys Ser Lys Gln Lys Arg Leu Ala Ile Cys  
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Leu Trp Cys Asp Gln Asp Gln Glu Ile Lys Asp Leu Tyr Tyr Tyr Ser  
 65 70 75 80

Ile Arg Thr Ser Ala Gln Ala Glu Ala Lys Lys Gln Gly Leu Glu Ser  
 85 90 95

Gln Val Ile Tyr Pro Ala Asp Pro Leu Pro Asp Pro Ala Ala Leu Ser  
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Gly Ile Ile Met Ile Gly Tyr Gln Gln Tyr Ser Pro Asp Arg Leu Asn  
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Glu Val Lys Lys Ser Gly Leu Pro Leu Val Phe Val Asp Thr Asp Thr  
 130 135 140

Leu Lys Leu Gly Tyr Cys Ser Val Val Ala Asp Phe Gly Gln Ala Met  
 145 150 155 160

Gln Glu Ala Leu Glu Val Phe Trp Gly Gln Gly Arg Glu Arg Ile Ala  
 165 170 175

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Asp Phe Arg Phe Arg Asp Tyr Lys Lys Ser Leu Ala Ala Arg Gly Gln  
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Tyr Asp Pro Asp Leu Val Tyr Val Gly Asn Phe Thr Pro Gln Ser Gly  
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Tyr Glu Ala Ile Lys Glu Ala Leu Lys Ser Gly Ser Phe Pro Lys Ala  
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 245 250 255

Lys Glu Ala Gly Ile Lys Val Pro Glu Asp Val Ser Leu Ile Ser Phe  
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 275 280 285

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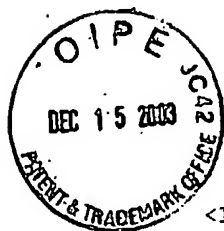
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<140> PCT/EP00/05834

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6 controlling gene transcription and/or expression in bacterial  
7 cells

9 &lt;130&gt; FILE REFERENCE: 112843-039

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C--&gt; 12 &lt;141&gt; CURRENT FILING DATE: 2002-05-13

14 &lt;150&gt; PRIOR APPLICATION NUMBER: 99112471.0

15 &lt;151&gt; PRIOR FILING DATE: 1999-06-30

17 &lt;160&gt; NUMBER OF SEQ ID NOS: 34

19 &lt;170&gt; SOFTWARE: PatentIn version 3.2

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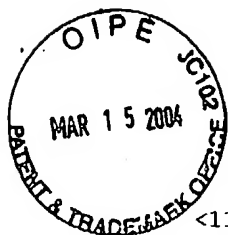
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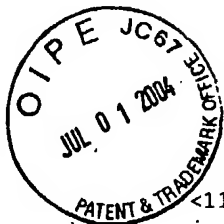
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His Val Glu Thr Gln Gln Met Gly Arg Ala Ser Val Lys Val Met Lys  
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IFW16

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PATENT APPLICATION: US/10/019,817C

TIME: 12:58:14

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4 &lt;110&gt; APPLICANT: Societe des Produits Nestle S.A.

6 &lt;120&gt; TITLE OF INVENTION: The Lactose operon of Lactobacillus delbrueckii and its use

for

7 controlling gene transcription and/or expression in bacterial  
8 cells

10 &lt;130&gt; FILE REFERENCE: 112843-039

C--&gt; 12 &lt;140&gt; CURRENT APPLICATION NUMBER: US/10/019,817C

13 &lt;141&gt; CURRENT FILING DATE: 2002-05-13

15 &lt;150&gt; PRIOR APPLICATION NUMBER: PCT/EP00/05834

16 &lt;151&gt; PRIOR FILING DATE: 2000-06-23

18 &lt;150&gt; PRIOR APPLICATION NUMBER: 99112471.0

19 &lt;151&gt; PRIOR FILING DATE: 1999-06-30

21 &lt;160&gt; NUMBER OF SEQ ID NOS: 33

23 &lt;170&gt; SOFTWARE: PatentIn version 3.2

25 &lt;210&gt; SEQ ID NO: 1

26 &lt;211&gt; LENGTH: 1435

27 &lt;212&gt; TYPE: DNA

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33	atggcaacga	tcagagaagt	ggccaaggca	gccggcgtgt	cgccagcgac	ggtttcccgg	180
34	gtcttgaact	atgaccagac	cctgtcggtc	aatgaggcaa	cgcggcagaa	gatattcaaa	240
35	actgctgaag	ccatgcacta	ccataagagc	cgaagacca	gaaagagcaa	gcaaaagcgc	300
36	ctggcgatct	gcctgtggtg	tgaccaagac	caggagatca	aggacctcta	ttactattca	360
37	atcagaacca	gcgcgaagc	agaggccaag	aagcagggac	ttgaaagcca	ggtcatttat	420
38	ccggctgatc	ctttgcccga	tccagctgct	ttaagcggga	ttatcatgat	tggctaccag	480
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PATENT APPLICATION: US/10/019,817C

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76 35 40 45
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80 50 55 60
83 Leu Trp Cys Asp Gln Asp Gln Glu Ile Lys Asp Leu Tyr Tyr Tyr Ser
84 65 70 75 80
87 Ile Arg Thr Ser Ala Gln Ala Glu Ala Lys Lys Gln Gly Leu Glu Ser
88 85 90 95
91 Gln Val Ile Tyr Pro Ala Asp Pro Leu Pro Asp Pro Ala Ala Leu Ser
92 100 105 110
95 Gly Ile Ile Met Ile Gly Tyr Gln Gln Tyr Ser Pro Asp Asp Leu Asn
96 115 120 125
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100 130 135 140
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111 Leu Leu Asp Gly Asp Leu Asp Ser Asn Phe Asp Lys Asn Asn Leu Val
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116 195 200 205
119 Tyr Asp Pro Asp Leu Val Tyr Val Gly Asn Phe Thr Pro Gln Ser Gly
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123 Tyr Glu Ala Ile Lys Glu Ala Leu Lys Ser Gly Ser Phe Pro Lys Ala
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